REMARKS

Claims 42, 45-53, and 55-57 are pending. Claim 43 has been canceled without prejudice, and Claims 1-41, 44, and 54 were previously canceled. Claims 46, 47, 49, and 50 are withdrawn from consideration as being drawn to non-elected inventions. Claims 42, 45, 48, 51-53, and 55-57 are being examined. Applicant has amended Claims 42, 48, 51, 53, and 55-57 as being directed to a composition comprising a purified and isolated nucleic acid molecule, said nucleic acid molecule encoding a human hepatitis C virus polypeptide having the amino acid sequence of SEQ ID NO: 3, and a method for inducing an immune response comprising the administration to an animal an effective amount of said composition to induce an immune response, and related compositions and methods. No new matter has been added. Reexamination and reconsideration of the application, as amended, are respectfully requested.

A. Compliance with 35 USC 112, second paragraph

As a preliminary matter, the Patent Office rejected Claims 42, 43, 45, 48, 51-53, and 55-57 under 35 USC 112, second paragraph, as being indefinite. Under MPEP 2173.02, the claims must be definite. Each of the claims was rejected as being indefinite in reciting the phrase "...said nucleic acid encoding a human hepatitis C virus having the amino acid sequence of SEQ ID NO:3..." It was unclear to the Patent Office how a viral particle that comprises elements obtained from a polypeptide comprising SEQ ID NO:3 can itself comprise SEQ ID NO:3. In response, the claims have been amended to make explicit what was implied, that said nucleic acid molecule encode a human hepatitis C virus polypeptide having the sequence of SEQ ID NO: 3. Under this amendment, the language of the claims explicitly states rather than implies definitive scope.

B. Compliance with 35 USC 112, first paragraph

The sole remaining issue is that the Patent Office rejected Claims 42, 43, 45, 48, 51-53, and 55-57 under 35 USC 112, first paragraph, as lacking enablement. According to MPEP 2164.08, enablement must be commensurate in scope with the claims. The rejection was

originally applied to Claims 43, and 55-57, the method claims. Upon amendment of Claims 42, 45, 48, and 51-53 to add the feature "pharmaceutical" to the composition claims, the rejection was extended to the composition claims. By this amendment, the feature "pharmaceutical" has been deleted from the composition claims. Additionally, by this amendment, the claims are directed to a composition comprising a purified and isolated nucleic acid molecule, said nucleic acid molecule encoding a human hepatitis C virus polypeptide having the amino acid sequence of SEQ ID NO: 3, and a method for inducing an immune response comprising the administration to an animal an effective amount of said composition to induce an immune response, and related compositions and methods. The patent specification demonstrates construction of an infectious clone of strain H77, which is genotype 1a (Spec. at Figs 1-3) and strain HC-J4, which is genotype 1b (Spec. at Figs. 5-13). See also the post-filing date art that published these results as Yanagi et al., Proc. Natl. Acad. Sci. USA 94:8738, 1997 (Exhibit 1), and Yanagi et al., Virology 244:161, 1998 (Exhibit 2). Although the ORF of the latter clone was from strain HC-J4, most of the 5' and 3' terminal sequence originated from strain H77, thus the latter clone was a chimera of genotypes 1a and 1b (Spec. at Fig. 11). The infectivity of the HCV clones was determined by in vivo transfection: viral nucleic acid was injected directly into the liver of chimpanzees, the transfection protocol being by laparotomy of RNA transcripts of strain H77 (Spec. at 40:21-22), and by percutaneous intrahepatic injection of RNA transcripts of strain HC-J4 (Spec. at 53:2-5). The conclusion was that genetically stable infectious clones of HCV could be constructed from both important genotype strains of HCV (Spec. at Exs. 4 and 8). Anti-HCV antibodies were detected in chimpanzees following transfection with the infectious cDNA clone of strain H77 (Spec. at Fig. 18B and Ex. 4A) and the infectious cDNA clone of strain HC-J4 (Yanagi et al. 1998 at Fig. 9). Albeit inconvenient, chimpanzees represent the quintessential animal model for HCV infection. (Yanagi et al. 1997, p. 8738, col. 2, ¶ 2; and Yanagi et al. 1998, p. 162, col. 1, ¶ 2). These data provide evidence that genetic immunization of hepatitis C virus transcripts induces an immune response. The scope of the claims being co-extensive with a method for inducing an immune response, enablement is commensurate in scope with the claims.

CONCLUSION

In view of the above, it is submitted that the claims are in condition for allowance. Reconsideration and withdrawal of all outstanding rejections are respectfully requested. Allowance of the claims at an early date is solicited. If any points remain that can be resolved by telephone, the Examiner is invited to contact the undersigned at the below-given telephone number.

Respectfully submitted,

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